## MCP SUPPLEMENTAL AMENDMENTS PUBLIC HEARING DRAFT COMMENT SETS IDENTIFICATION TABLE

Comment Set Number	Written or Oral	Name and Affiliation of Person(s) Who Submitted Comments
1	Written	Joanne Perwak, Shaw Environmental & Infrastructure
2	Written	Paul McManus, EcoTec Inc.
3	Written	Bruce Smith and Joan Laurenti
4	Written	F.R. Ruehe, Department of the Navy
5	Written	David Begelfer, National Association of Industrial and Office Properties, Massachusetts Chapter
6	Written	Peter Romano, Independent Oil Marketers Association of New England
7	Written	Bruce Ross, Kleinfelder East, Inc.
8	Written	David MacDonald, LSP Association
9	Written	Laura Kelly and Elliot Steinberg, Haley & Aldrich, Inc.
10	Written	Ned Abelson, Goulston and Storrs
11	Written	Ray Leather, Drake Petroleum Company, Inc.
12	Oral/Lakeville Hearing	Steve Lemoine, SAGE Environmental
13	Oral/Lakeville Hearing	Bill Hoyerman, Coler & Colantonio, Inc.

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Pilot Test Definition, 40.0006	Clarify that 21 days applies to active testing (not analytical).	5	Clarification made.
	Expand to allow test up to 6 months and to allow other remedial alternatives and technologies. Such expansion would allow resources to go toward the development of the remedial technology, rather than to the submittal of RAM Plans, Status Reports and Completion Statements.	8	Neither the time period nor list of allowable activities was expanded. While MassDEP supports the goal of directing resources to remedy development, it considers the 6-month time period too long for the operation of a Pilot Test without submission of a plan to MassDEP. While the comment suggests that "other remedial alternative and technologies" might be included under the definition, no specific recommendations were provided.
	Supports proposed change for reasons provided by MassDEP	11	Change was made as proposed with clarification that analytical time does not count toward the 21 days.
Electronic Submittals, 40.0008 & 40.0015	Do not eliminate the grace period even after all affected submittals are required to be made electronically. Grace period facilitates compliance, which is good for everyone involved with the MCP system.	5, 8, 10	MassDEP will not eliminate the grace period at this time.
	Delay implementation of mandatory electronic submittals for another year to January 1, 2009, or include a one-year phase in period to ensure a smooth transition.	5, 8	Implementation of mandatory electronic submittals was changed to January 1, 2009.
Remedial Monitoring Report, 40.0027	Support eliminating RMR for fans, air handling system.	5,11	The RMR requirement was eliminated for window fans, but not for air handler systems or other remedies/systems.
	Supports eliminating RMR for fans to vent oil spills, but does not support eliminating RMR for air handler systems at other types of VOC sites. At a minimum, these systems should be monitored monthly to check flow rate and damper settings and maintained on a quarterly basis.	7	

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	Don't standardize submittal dates. While it would simplify the due dates, it would be burdensome to LSPs and PRPs with multiple sites; site-specific submittal dates spread the workload. Over time, LSPs and PRPs have developed tracking systems to manage due dates.	7,12	Submittal dates were not standardized; proposal was withdrawn.
	<ul> <li>Language in 40.0027(1) is awkward; revision suggested.</li> </ul>	5	Suggested revision is not consistent with intent of 40.0027(1); no change was made to the current language.
Well Maintenance and Security, 40.0028	Provision appears to be about well construction and not about well maintenance and security. MassDEP should address this discrepancy between title and provision.	5	MassDEP disagrees with the comment. The reference to "Any well installed or constructed for the purpose of sampling" is only intended to define those wells subject to the well maintenance and security provision; otherwise the provision in unrelated to well construction.
	Concurs that the security and integrity of wells should be maintained during their period of service; MassDEP should recognize, however, that harsh winter conditions may damage wells; issuing NONs for such damage would be a severe approach for promoting well integrity. Recommend a periodic inspection and repair provision, so that damage may be corrected without MassDEP issuing NONs.	8	Conducting inspections and repairs, as necessary, is already implicit in the proposed provision, i.e., in order to ensure the well integrity, inspections and repairs would need to occur on an ongoing basis. No change was made to the proposed language.
	Supports proposed change as a matter of good policy.	11	No change was made to the proposed language.
	Define security and reference what the best management practices are.	12	The provision provides a clear performance standard.  MassDEP agrees that information on best management practices would be useful, but believes such information is more appropriately handled in guidance.
Remedial Additives, 40.0046	Pre-application sampling (where multiple applications are made) – change from once a month to once every three months.	5	No change was made to the proposed language.  MassDEP believes the monthly interval strikes an appropriate balance between monitoring groundwater conditions and reducing the sampling and analytical costs.

#### MassDEP's Response to Public Comments on the MCP Supplemental Amendments Public Hearing Draft Summary of Comment MassDEP's Response to Comment as Addressed in the **Public Hearing Draft** Comment Section & Provision Set(s) ID # **Final Amendments** Supports the proposed change. 8, 11 Although not out for comment, the post-MassDEP is not prepared to make a change to this provision without further consideration and public review application sampling is too prescriptive. and comment. MassDEP's Release Prevention and Response Planning Release Prevention 5 Do not include this authority in the MCP authority will be added to the MCP to reflect this statutory and Response (authority already exists in the statute) Planning, 40.0101(u) authority in the regulations. The inclusion of this authority May result in other regulatory programs in the regulations does not provide the basis for importing being imported into the MCP. other regulatory programs into the MCP. MassDEP's Release Prevention and Response Planning 8, 11 Do not include this authority in the MCP. authority will be added to the MCP to reflect this statutory The proposed language is too vague, and/or the prevention of releases is authority in the regulations. The proposed language has been redrafted for clarity. M.G.L. c. 21E, s. 6 specifies adequately regulated under various local, state and federal requirements. that requirements imposed under this section cannot duplicate the requirements of other MassDEP programs. Notification Exemption, Suggested change was not made; the exemption is Expand exemption to other heavy metals. 40.0317(22) Allow LSPs to use technical justification to appropriately limited to those soils where elevated support not notifying due to the presence concentrations of specific metals is well documented and of naturally occurring heavy metals. consistently observed. LSPs are not necessarily involved at the time of notification and therefore would not necessarily be involved in judging whether metal concentrations were naturally occurring. Expand to nickel. Based on its review of metals concentrations in Boston 5 Blue Clay provided by Haley and Aldrich, MassDEP concurs that it is appropriate to extend the exemption to nickel; nickel is frequently present at concentrations above the Reportable Concentrations in Boston Blue Clay. MassDEP did not raise the RCS-1 for nickel. OHM levels from naturally occurring sources may still pose a risk when

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matter of good policy.

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Re-establishing response action deadlines for new parties ("White Knight" proposal), 40.0570	Support the proposed section but recommends that MassDEP make it clear that fees previously incurred by the former site owner do not become the obligation of the new site owner.	5, 8	No change was made to the proposed language regarding the fee issue. However, the Department does not intend to collect fees that were previously incurred by a former site owner from a new site owner who complies with this section.	
			Also, the first paragraph was modified to make clear that this section does not apply to Eligible Persons, Eligible Tenants or Other Persons who have previously submitted a Tier I Permit Application or Tier II Classification Submittal.	
Permit Extension and	Support proposed change.	5,11	No change was made to the proposed language.	
Tier II Classification Extension Effective Term Consistency, 40.0560(d) 40.0702(5) 40.0706(1) 40.0751(3)	Supports proposed change. The "Note to Reviewer", however, implies that an expired Permit is a condition of non- compliance. This is not always the case. For a Class C-1 RAO, a Permit Extension is not necessary; this continues to be a point of confusion and should be clarified.	8	The "Note to Reviewer" was referring to scenarios where maintenance of a Permit or Tier II Classification is necessary; the comment is correct in pointing out that in the case of Class C-1 RAOs, current Permits or Tier II Classifications are not required (the same is true for disposal sites with Remedy Operation Status).	
Phase IV Remedy Implementation Plan Submittal, 40.0870	Supports proposal described in Note to Reviewer, but notes that no proposed language was provided.	5	Added provision at 40.0871(6) to require the submittal of a complete Phase IV RIP prior to conducting the Comprehensive Remedial Action.	
	Supports the proposed change. It is assumed that the requirement for the submittal of a Phase IV RIP would still allow IRAs and RAMs to continue per their filed plans.	8	IRAs and RAMs may continue per previously filed plans. As a plan for conducting a Comprehensive Remedial Action for the disposal site, however, the Phase IV RIP should at a minimum reference ongoing remedial activities covered by previous plans, and as appropriate, incorporate those activities into the Phase IV RIP.	
	The Department should take this opportunity as it adds this requirement related to the Phase IV RIP to clarify that parking lots and driveways constructed in conjunction with site buildings do not constitute remedial actions.	5	Comment is not directly related to the proposed revision. Parking lots and other paved areas may or may not be part of a remedy, depending on the site-specific circumstances and whether the pavement serves to eliminate exposures.	

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Phase V Status Report Submission Schedule for Remedies Initiated in Earlier Phases, 40.0892(3)(c)	Support proposed change.	5,8,11	No change was made to the proposed language.
Petroleum Hydrocarbons in GW-1 Areas, 40.0924(2)(b)3.	Public water supply well locations are not provided on MassDEP GIS maps. The proposal requires knowing the well locations in order to know whether criteria are met at a distance greater than 1,000 feet from the public water supply well.	1	Information on well locations is made available to LSPs upon request.
	MassDEP should make it clear that the proposal applies in Aquifer Protection Districts (APDs) that lie outside of both a Zone II and a PPA.	5	Comment is not consistent with the intent of the proposal. Aquifer Protection Districts that are unassociated with an existing well (i.e., do not overlay a Zone II or are not contiguous with a Zone II) represent areas of protection for potential future water supply sources. The "Petroleum in GW-1 Areas" provisions are directed at disposal sites in Zone IIs and Aquifer Protection Districts surrounding existing water supply wells. No change was made to the proposed language related to this comment.
	MassDEP should provide guidance to municipalities with APDs to ensure that their language reflects MassDEP's intent with the proposed changes in this section.	11	The proposed changes are consistent with the intent of protecting groundwater quality for use as drinking water in APDs that surround current wells and do not conflict with by-laws to protect these aquifers.
	Proposal should not be limited to Oil; it should extend to additives, including MTBE. The limitation to Oil is likely to exclude all gasoline and many fuel oil releases.	8	The proposal was not extended to additives. The proposal was premised on the well-documented biodegradation of petroleum fractions. The biodegradation and fate and transport properties of additives are not as predictable.
	The provision should require the completion of a Phase II Comprehensive Site Assessment, in addition to the assessment endpoints listed.	8	The provision was changed to add the submission of a Phase II Report as a requirement.

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	Replace "non-detect" with "below CAM Reporting Limits for the GW-1 setting".	5,8	"Non-detect" was replaced with "not detected at or above analytical limits appropriate for a GW-1 area".
	The exclusion of sites that have impact to bedrock is overly restrictive. Impact to a public water supply via migration to and through bedrock is highly unlikely, as most public water supply wells are overburden wells.	8	The bedrock exclusion was retained. This provision is limited to those situations where the potential impact to public water supply wells can be demonstrated with certainty. Contaminant migration through bedrock is unpredictable and therefore does not allow for such a demonstration.
	Recommends that the NAPL exclusion be revised to allow for the assessment of NAPL in accordance with the American Petroleum Institute for LNAPL. LNAPL present at or below residual saturation concentration is immobile and does not present a threat.	11	The NAPL exclusion was modified to "NAPL is not present at a thickness equal to or greater than ½ inch in any environmental medium" (consistent with the UCL NAPL provision).
Petroleum Hydrocarbons in GW-1 Areas, 40.0926(8)	The requirement to show diminishing concentrations based on quarterly monitoring after operation of an Active Remedial System is stopped is a pretty specific circumstance. The regulations don't address a timeframe for situations where an Active Remedial System is not used.	1	The requirement was changed to demonstrating diminishing concentrations after the termination of any Active Remedial System, if such a system was used, and after the achievement of the required concentrations; this change addresses situations where there was no Active Remedial System used.
	The requirement for 4 years of quarterly data will require, in most cases, that a Class C RAO be filed prior to eventual Class A or B RAO. Once a Class C RAO is filed, the impetus for achieving a Class A or B RAO may be diminished. Suggests changing requirement to 2 years of quarterly monitoring.	5	The fact that some parties may have to file Class C RAOs should not determine the period of monitoring, rather the monitoring period should be based on what is sufficient to confirm the achievement of groundwater concentrations and account for seasonal variability. The requirement was changed to showing diminishing concentrations confirmed by a minimum of two years of quarterly monitoring after the termination of any Active Remedial System and after

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	<ul> <li>4 years of quarterly monitoring is too conservative; filing a Class C RAO or ROS would likely be necessary prior to achieving a Class A or B RAO.</li> <li>Sites where a Class C RAO has been filed that have been monitoring for years but on a frequency less than quarterly could not apply this provision for another 4 years. Some consideration should be given to past monitoring data that is not quarterly; in such cases, one year of additional quarterly or temporal sampling should be sufficient to confirm historical trends.</li> </ul>	7	the achievement of the required concentrations, because MassDEP believes that two years may be sufficient in many cases for such a demonstration.
	4 years of monitoring is burdensome relative to maintaining a Permit. There should an exclusion from the Permit Extension requirements if the disposal site enters the required monitoring phase.	8	The monitoring requirement was changed from 4 years to a minimum of 2 years. Even at 2 years, Permit and Tier II Extensions may be necessary. MassDEP did not change the proposed regulation to eliminate the extension requirement for sites in the monitoring phase. ROS is available for such sites where there is indeed a high likelihood that a Permanent Solution can be achieved; Permit/Tier II Classification Extensions are not required for sites with ROS.
	Requirement for quarterly monitoring is too prescriptive and burdensome. Period of adequate monitoring should be left to the discretion of the LSP.	13	MassDEP believes it is appropriate to specify a minimum number of monitoring rounds to ensure adequate characterization of seasonal variability, achievement of groundwater concentrations, and protection of public water supply resources.

#### MassDEP's Response to Public Comments on the MCP Supplemental Amendments Public Hearing Draft Summary of Comment MassDEP's Response to Comment as Addressed in the **Public Hearing Draft** Comment Section & Provision Set(s) ID # Final Amendments MassDEP agrees that further definition of the performance The requirement to show decreasing concentrations throughout the plume is standard for meeting this requirement is warranted. This too vague and does not establish an type of detail is more appropriately handled in guidance. appropriate performance standard. A more specific definition of what is and is not a decreasing trend is required. A method to account for normal and expected temporal variation should be included in the regulation. No change was made to the proposed language. Zone A Exception Support proposed change. 5.8 (Where Lack of a Hydrologic Connection is Demonstrated), 40.0932 **AUL Notice to Interest** Supports shortening the time period, but 5 No change was made to the proposed language/timeframe. MassDEP believes that shortening Holders Timeframe believe the change is insufficient and (Shortened from 45 – should be shortened further to 21 days; in the timeframe further would not afford interest holders 30 days), adequate time to become familiar with and understand the practice this notice period adds 40.1074(1)(e) implications of the AUL with respect to their interests in the considerable complications to the disposal site property. process of preparing and recording an AUL. Supports proposed change. 8 The proposed change is not enough. 10 The notice is not a request for comments, so 21 days is sufficient: 21 days is also consistent with other MCP timeframes. 5 Procedures for Liens. No substantive change was made to the proposed No specific comments on the proposed 40.1250 language. changes. Supports proposed changes. 8 Public Involvement 8,11 No change was made to the proposed language. Support proposed change. Provisions. Notice of Sampling, 40.1403(10)

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Public Involvement Provisions, Notice of Affected Individuals, 40.1403(11)	The term "any person conducting a remedial action" could be interpreted as implying that the LSP has a duty, separate and distinct from the RP, PRP or Other Person, to provide Notice to Affected Individuals.	5	The existing provision at 40.1402(3) makes clear that the LSP is not responsible for this or other notices required pursuant to the public involvement provisions of 310 CMR 40.1400. 40.1403(2) states "At any disposal site at which a RP, PRP or Other Person is conducting a response action, that RP, PRP or Other Person shall be responsible for all Public Involvement Activities pursuant to M.G.L. c. 21E and this Contingency Plan."
	Supports proposed change.	11	No change was made to the proposed language.
Public Involvement Provisions, Notice to Property Owners within the Boundary of a Disposal Site, 40.1406	Recommends that the language be prescriptive of the type of alternative notice to be provided and that the requirement to consult with the Department be eliminated.	5	The language was not made more prescriptive. The proposed language provides flexibility to use different means of alternative notice. The requirement to seek MassDEP's approval of the means of alternative notice was retained. MassDEP believes its involvement in such cases is appropriate and can facilitate communication with local officials, and that its approval can be provided in a timely manner.
	Recommends that the number of property owners receiving notice allowing for alternative means of notice be reduced from 75 to 25 or more.	8	The number of property owners was reduced from 75 to 50. This is consistent with 40.1406(1)(c), which requires prior written notice to MassDEP and the Board(s) of Health in the community(ies) in which the properties are located if the number of property owners to receive written notice exceeds 50.
	Recommends that the provision be more flexible regarding providing advanced notice of sampling. For example, one notice with a schedule for subsequent sampling should be sufficient, rather than a separate notice prior to each subsequent sampling event.	8	The proposed language already incorporates the flexibility sought; 40.1406(10)(d) states that "an alternative schedule may be established for providing the results of multiple sampling events" provided that it is established in writing and agreed to by the property owner. Where such alternative schedule is established, prior notice of each event could be waived and results could be compiled and provided to the property owner on a less frequent basis.

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	Supports proposed change.	11	No substantive change was made to the proposed language other than the threshold number of property owners for seeking alternative means of notice described above.
Technical Assistance Grants, 40.1452(5)	The provision should be revised to allow TAGs related to Tier ID (default) sites where there is information equivalent to what would be needed to Tier Classify the disposal site.	2	For the great majority of Tier ID sites, information equivalent to what would be needed to Tier Classify the disposal site is not available. Limiting eligibility to Tier Classified sites ensures that the grants are applied to disposal sites with sufficient information on the nature and
	<ul> <li>No specific comments on proposed changes.</li> </ul>	5	extent of contamination to make the TAGs worthwhile.  TAGs would be available to Tier ID disposal sites once  Tier Classification occurs.
	Supports proposed changes. They ensure that groups will use grants for assistance reviewing information related to active sites.	8	NOTE: The TAG amendments in the Supplemental MCP Amendments public hearing draft were made final effective July 13, 2007. MassDEP decided to finalize these amendments ahead of the other Supplemental MCP Amendment proposals to ensure that the TAG related changes were in effect near the start of the fiscal year as the TAG process starts and runs with the fiscal year.
Numerical Ranking System VPH/EPH	Supports proposed changes.	5	No change was made to the proposed values and scores.
Mobility and Persistence Values and Scores, 40.1514(2)	The table indicates that C19-C36 petroleum fractions are persistent. This is inconsistent with MassDEP's Policy #WSC-04-160 "Conducting Feasibility Evaluations Under the MCP" which considers all petroleum types and fractions non-persistent, with the exception of No. 6 oil.	8	The NRS mobility and persistence scores and the Feasibility Policy apply to different issues. The NRS score is used to score the relative seriousness of the disposal site at the time of Tier Classification. The Feasibility Policy provides guidance on evaluating the costs and benefits of additional remediation to achieve background concentrations. While the Feasibility Policy could have made distinctions between the persistence of different fractions, it instead grouped them generically to simplify and standardize the feasibility evaluation with respect to petroleum sites.

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Numerical Standards, 40.0900, RDX	More accurate information is available on which to base a proposed RDX standard. Therefore, MassDEP should delay the setting of an RDX level until this new data is integrated into the USEPA IRIS database.	4, Point Paper, Intro	MassDEP acknowledges the new information that the Army Center for Health Promotion and Preventative Medicine (CHPPM) has developed. Presently, MassDEP has not set toxicity values for RDX and relies on existing USEPA IRIS toxicity values. If and when USEPA modifies IRIS values, which are under USEPA review, MassDEP will reconsider its toxicity value and MCP standard. Until then, MassDEP will continue to rely on the USEPA IRIS value for deriving RDX cleanup standards.	
Numerical Standards, 40.0900, RDX	MassDEP should change the descriptor of RDX from "possible human carcinogen" to "suggestive evidence of carcinogenic potential."	4, Point Paper, page 8	USEPA classifies RDX as a possible human carcinogen.  MassDEP will reconsider the status of RDX as a possible human carcinogen when USEPA completes its RDX review.	
Numerical Standards, 40.0900, RDX	The carcinogenicity of RDX is equivocal as it caused tumors only in female mice and not in male mice or rats of both sexes.	4, Point Paper, pages 1 and 2	MassDEP & USEPA consider dose-related tumor outcomes, even for a single sex & species, in its toxicity evaluations for chemicals. USEPA classifies RDX as possibly carcinogenic to humans and continues to list a cancer slope factor on IRIS.	
Numerical Standards, 40.0900	Because of the hepatocellular sensitivity of the B6C3F1 mouse, the cancer bioassay pathology slides were reassessed using current tumor classification criteria. Tumors were still determined to be present but the numbers at all doses were lower than	4, Point Paper, pages 2 and 4	The new pathology assessment did result in somewhat lower tumor numbers. However, treated groups continued to exhibit tumors in excess of controls.  In keeping with USEPA guidance (USEPA 2005), as tumors were observed at all dose levels and the	
	previously estimated. Moreover, the highest dose exceeded the Maximum Tolerable Dose (MTD) and results from this dose should be discarded.		mechanism of tumor induction is not known at all, there is no basis to discard the results (tumors) observed at the highest dose tested.	
Numerical Standards, 40.0900	The cancer bioassay pathology results were not significant when compared to historical controls.	4, Point Paper, page 3	According to USEPA guidance (USEPA 2005), it is preferable to use the data from treated and control animals from the same study. Historical control data is interesting but less preferable to use for toxicity assessments.	

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Numerical Standards, 40.0900	The pathology data from the reassessment should be used to estimate a cancer slope factor for RDX, if one is estimated at all.	4, Point Paper, page 8	Depending on USEPA's review of the new pathology data, this reassessment may be appropriate. See additional comments below, where MassDEP used the new pathology data to derive potency estimates.	
Numerical Standards, 40.0900	Suggests a cancer slope factor calculated by DOD using the new pathology data and the US EPA's benchmark dose (BMD) model. The cancer slope factor calculated by DOD based on the BMD <sub>0.1</sub> is 3.2x10 <sup>-2</sup> mg/kg/d, about 3-times less potent than the current cancer slope factor used by USEPA and MassDEP (1.1x10 <sup>-1</sup> /mg/kg/d).	4, Point Paper, page 8, Attachments 3 and 4	DOD's calculation did not follow the protocol recommended by USEPA. The cancer slope factor derived by DOD is based on the benchmark dose (BMD) and not the benchmark dose low value (BMDL), the appropriate approach according to USEPA protocols.  Using the appropriate BMDL approach would result in a cancer slope factor higher than the cancer slope factor that is currently on IRIS.  If USEPA determines RDX causes cancer through a nongenotoxic mechanism, the tumor data, with appropriate uncertainty factors, could result in a risk-based GW-1 value of below 1 µg/L.	
Numerical Standards, 40.0900	The standard for RDX should consider the significant new non-cancer science that should be available in the fall of 2007.	4, Point Paper, page 13, Attachment 7	MassDEP will review this information when it is available. The decision to use an RfD instead of a cancer slope factor will depend on the characterization of RDX as a carcinogen. USEPA will be evaluating the new DOD provided information but has not changed or withdrawn its IRIS cancer value.	
Numerical Standards, 40.0900	The endpoint used by USEPA to derive the current non-cancer RfD (3x10 <sup>-3</sup> mg/kg/day) is inappropriate as the observed effect on the prostate is not a result of RDX toxicity as such an effect was not observed in other studies and was not replicated in their recent work. DOD included the results of a 90-day study conducted by the CHPPM (2006) with its comments.	4, Point Paper, page 10, Attachment 7	MassDEP's final standards take into account information on the carcinogenicity and non-cancer toxicity of chemicals. As noted above, USEPA has determined that cancer bioassay tests indicate that RDX is possibly carcinogenic to humans and has derived a cancer slope factor. Putative standards for RDX based on the observed cancer effects, assuming either a genotoxic or nongenotoxic mechanism, are lower than would result from the use of the non-cancer endpoint data and thus drive the final MCP risk-based value. This ensures protection of the public from cancer and non-cancer effects.	

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Numerical Standards, 40.0900	The Army has collected an extensive dataset on exposure of human populations to RDX contaminated soil, uptake of RDX into garden vegetables, game animals and other potential sources of uptake to support the calculation of a new Relative Source Contribution Factor (RSC). The data will be available in late 2007.	4, Point Paper, page 12	The risk component of MassDEP's proposed RDX standard is based on carcinogenicity (using USEPA's cancer slope factor). An RSC is not used in these cases.
Numerical Standards, 40.0900	A metabolism study was conducted in Yucatan minipigs. Two major metabolites and three minor putatively toxic metabolites were identified. CHPPM stated that the minor metabolites are artifacts formed after collection of urine (in the sample and not from metabolism in the animals). DOD is also conducting several studies to support derivation of a new Physiologically Based Pharmacokinetic (PBPK) model of distribution model for RDX.	4, Point Paper, page 6	The metabolism studies and DOD's PBPK model development are of interest to MassDEP and may ultimately help in extrapolating results among species. At this time, however, the available data is not sufficient to reach firm conclusions. For example, comparative metabolism studies in rodents, minipigs and humans are limited and the attribution of the minor metabolites observed in urine to sample collection and handling artifacts is not well supported.
Numerical Standards, 40.0900	The inhalation reference dose of 0.12 mg/m <sup>3</sup> for 1,4-dioxane is from the 1992 version of HEAST. There are no inhalation toxicity values on IRIS or the most current version (1997) of HEAST. MassDEP should present a more detailed discussion of the toxicity information to justify the use of the 0.12 mg/m <sup>3</sup> inhalation reference dose.	4, Additional Specific Comments.	The reference cited in the spreadsheets for the source of this toxicity value is incorrect. This value is not from HEAST, but rather from MassDEP's 1990 report titled Chemical Health Effects Methodology and the Method to Derive Allowable Ambient Limits. The inhalation RfC-equivalent value of 0.12 mg/m³ was obtained by multiplying the 1,4-dioxane threshold effects level (TEL) of 24 µg/m³ published in Table III-6 of the report by 5 to eliminate the source contribution factor incorporated into the TEL. The report documents the basis for the TELs, and it can be found at <a href="http://mass.gov/dep/service/compliance/riskasmt.htm">http://mass.gov/dep/service/compliance/riskasmt.htm</a> .

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Numerical Standards, 40.0900	There are no inhalation-based toxicity values for HMX or RDX on IRIS or HEAST. The RfCs are based on route-to-route extrapolation from oral RfDs. MassDEP should present a detailed discussion of the appropriateness of this evaluation for these substances.	4, Additional Specific Comments	When no inhalation toxicity values are available for a compound that is expected to partition from groundwater into indoor air to an appreciable extent, MassDEP uses route-to-route extrapolation as a matter of practice to estimate an inhalation toxicity value from an oral toxicity value. There are a number of sources of uncertainty associated with this procedure, but its use is justified in the absence of alternative toxicity information.  MassDEP plans to develop or identify inhalation toxicity values for a number of substances within the next few years, including HMX and RDX. MassDEP plans to focus resources on the basic research necessary to develop
			new values rather than an extensive review and summary of the sources of uncertainty about the current values.
Numerical Standards, 40.0900	The Henry's Law Constant used in the MassDEP spreadsheet for RDX is 6.32E-08 atm-m³/mole at 20 degrees Celsius and the source is <a href="http://www.syrres.com/esc/physdemo.htm">http://www.syrres.com/esc/physdemo.htm</a> . This value appears to be incorrect. The value on the website is 2.01E-11 atm-m³/mole at 20 degrees Celsius.	4, Additional Specific Comments	The reviewer is correct. The Henry's Law Constant shown in the spreadsheet has been corrected.

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Numerical Standards, 40.0900	Although not included in these changes, the reviewer requests that MassDEP reconsider its position on the toxicity values used to derive the Method 1 standards and Reportable Concentrations for PCE. This reconsideration request was made with the April 2006 changes and MassDEP did not provide a well-supported reason for not reconsidering its position on the toxicity values. The current, extremely conservative values are making it very difficult to manage compliance with the MCP at almost any site where PCE is present.	5	The comment presumably refers to the GW-2 standard, which considers MassDEP's inhalation unit risk factor (URF). MassDEP's URF is lower than the URFs used by some other agencies. Although the GW-2 standard considers the URF, it is actually based on a generic indoor air background concentration and a chemical specific application of the Johnson & Ettinger model. The change in the GW-2 standard that came into effect in April 2006 is due to (1) switching to a chemical-specific, rather than generic, application of the model; and (2) updating the Henry's Law Constant.  USEPA is expected to publish a draft report on PCE toxicity in the near future and a subcommittee of the National Academy of Sciences (NAS) will subsequently review and discuss the data. MassDEP intends to review the USEPA and NAS reports to determine whether a change in the URF used by MassDEP is warranted.
Reportable Concentrations, 40.1600	PCBs RCGW-1: The proposed change in GW-3 is listed as the basis for the proposed change to 0.5 μg/L for RCGW-1. However, the proposed GW-3 standard is 10 μg/L. Is this a contradiction? In light of this apparent contradiction (also noted for chloroform and acenaphthylene), all proposed RC's should be reviewed.	5	There is no contradiction. The current RCGW-1 is based on the current GW-3 of 0.3 $\mu$ g/L, because the GW-3 value is the lowest of the groundwater standards (RCGW-1 is based on the lowest of the three standards). As a result of the proposed change in GW-3 from 0.3 to 10 $\mu$ g/L, the GW-1 standard of 0.5 $\mu$ g/L becomes the lowest of the three standards. The RCGW-1, consequently, is now based on the GW-1 standard, because of the change in the GW-3 standard. A similar situation occurred with chloroform, but not with acenaphthylene.
Numerical Standards, 40.0900	The duration adjustment factor for less than continuous exposure to n-hexane (5d/7d) during the toxicity study is inappropriate (for calculating the RfD).	6 Attachment, page 2	The duration adjustment process is not unique to n- hexane. It is a process applied by regulatory agencies to every chemical that needs duration adjustment in the derivation of RfDs and RfCs.
Numerical Standards, 40.0900	The critical study used (Krasavage, 1980) to derive the RfD evaluated only subchronic effects.	6 Attachment, page 2	Subchronic studies with proper adjustment factors are routinely used by regulatory agencies to derive RfDs and RfCs when chronic data are lacking.

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Numerical Standards, 40.0900	The study (Krasavage 1980) on which the n-hexane RfD is based used a small sample size, and several test animals per group died during the exposure period.	6 Attachment, page 2	MassDEP is aware of the limitations of the data described by the reviewer, however, the peripheral neurotoxicity observed in the orally treated surviving rats was consistent with the effects observed in humans and animals exposed to n-hexane by inhalation. At this time, the Krasavage study is the only oral study that is available. Until new and relevant studies become available, Krasavage provides the best basis to derive an RfD for the $C_5 - C_8$ aliphatic fraction. The value is supported by the results derived by converting the inhalation RfC of 0.2 mg/m³ developed for $C_5 - C_8$ aliphatic fraction into an oral dose by assuming a 70 kg person inhaling 20 cubic meters of air per day, which results in an oral dose of 0.06 mg/kg/day. This is close to the RfD of 0.04 mg/kg/day derived from the oral study of Krasavage.
Numerical Standards, 40.0900	The toxicity of n-hexane is realized through metabolism of n-hexane to the gamma diketone, 2,5-hexanedione; toxicity is, therefore, directly correlated with the concentration of 2, 5-hexanedione. In laboratory animals (rats, mice) the major metabolite of n-hexane is 2-hexanol versus the diketone, which is the primary metabolite in humans (EPA 2005). Thus, the interspecies extrapolation derived from animal studies may not be appropriate in humans.	6 Attachment, page 3	The comment is unclear but could be interpreted as suggesting that rats are less sensitive to n-hexane than humans, and that the RfD may not be protective enough. However, data on systematically performed comparative metabolic studies between humans and rats are lacking. The high levels of 2,5 hexanedione observed in humans have been suggested to be the result of an artifact resulting from treatment of urine samples with acid to hydrolyze urinary conjugates. Until good data on the comparative metabolism of n-hexane in humans and rats are available, the Krasavage study with an interspecies adjustment factor of 10 continues to be an appropriate basis to derive an RfD for the fraction.
Numerical Standards, 40.0900	The toxicity exhibited by n-hexane is unique among other compounds representative of 5 – 8 carbon aliphatics, such as n-heptane.  N-hexane typically comprises only a relatively small fraction of petroleum mixtures.	6 Attachment, page 3	The issues concerning these comments are extensively discussed in the total petroleum hydrocarbon document entitled "Updated Petroleum Hydrocarbon Fraction Toxicity Values for the VPH/EPH/APH Methodology, Section 2.1.1, pg 3–20. The document is available at <a href="http://www.mass.gov/dep/cleanup/laws/tphtox03.pdf">http://www.mass.gov/dep/cleanup/laws/tphtox03.pdf</a> .

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Numerical Standards, 40.0900	The proposed increase in xylene GW-3 standard does not go far enough. MassDEP should revisit the appropriateness of the Coho salmon toxicity study and use of and reliance on avoidance as an ecological endpoint for standard setting.	6	MassDEP believes the use of the lowest published effect level is justified; it may not even protect the more sensitive species at a site because many fewer species are tested than are present in the environment.  Avoidance is a valid endpoint because it indicates the concentration at which the habitat is uninhabitable.  MassDEP's ecological risk characterization guidance considers habitat degradation as a condition of significant risk.
Numerical Standards, 40.0900	The reviewer submitted comment letters from two consulting firms (Menzie-Cura & Associates and Woodard and Curran), and cited these submittals as presenting a compelling case for the Commonwealth to refrain from any further numerical standard changes until such time as more scientifically defensible toxicological studies for PAHs are conducted and published in the scientific literature.	6	The reviewer overstates the recommendations contained in the consultant letters. Neither letter suggests that MassDEP generally refrain from further numerical standard changes in the short or long term. MassDEP has responded to the consultants' specific comments on the standard setting approach in other responses in this summary.

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Numerical Standards, 40.0900	The documentation of the leaching model used to derive soil standards and the rationale as to why the variables used in the new approach are better than those used the previous approach is lacking. Specifically, the values for Dispersion Coefficient, Volatilization Factor and Disconnectedness Index are questioned.	6	As the poster "Evaluation of MCP Soil Standards: A Probabilistic Approach" (Mohanty 2006, referenced in the Woodard & Curan attachment) indicates, there are several reasons why the values of physical constants used in the new approach are better than those used in the previous approach. The old approach used a single conservative value for input parameters, rather than a possible range of values, and a single equation to derive dilution/attenuation factors (DAFs) based on a correlation with KOC (organic carbon partitioning coefficient) and HLC (Henry's Law Constant). Where possible, the new approach uses actual values measured at sites in Massachusetts, and is more chemical specific.  Lacking sufficiently generic empirical data, the Volatilization Factor was conservatively set to one. The Disconnectedness Index is used to correlate the modeled recharge rate with an observed recharge rate at a specific site. Since the model results are supposed to be generic, it would be inappropriate to calibrate the model to site-specific data. The selection of the dispersion coefficients can be found in the footnote to Mohanty 2006, and also in Appendix 5 of the EPH/VPH Implementation Guidance.
Numerical Standards, 40.0900	The selection of percentiles used to generate the resulting Dilution and Attenuation Factors (DAFs) from the Leaching Model are "relatively arbitrary."	6	The percentiles, used to select the DAFs, were chosen in an effort to be protective but not overly conservative. A single value is needed to develop the MCP standard. Site specific flexibility is available in the MCP under Method 2 or 3.
Numerical Standards, 40.0900	In the public hearing draft, the proposed change for the Ethylbenzene S-3/GW-2 standard is listed as the result of a "change in basis from Ceiling Value to Professional Judgment". The MCP Toxicity.xls spreadsheet, however, lists the basis for the change as "Leaching".	6	The public hearing draft is incorrect; the proposed standard is indeed based on leaching.

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Numerical Standards, Acenaphthylene, 40.0900	Recommend using the value reported for acenaphthene or phenanthrene as a surrogate rather than the median phototoxicity value for all PAHs.	5,6,8	Phototoxicity information was not available for all PAHs. If toxicity data were available (whether or not it was phototoxicity data) for a particular PAH, then it was used. If no data were available for a chemical, then the median value from available PAH phototoxicity data was used. Neither acenaphthene nor phenanthrene had available phototoxicity data, so using data from tests on these chemicals would be contrary to MassDEP's procedure. Further, there is evidence that acenaphthylene can cause phototoxicity. Schirmer et al (1998) observed photocytotoxicity when a cell line from a rainbow trout gill was exposed to acenaphthylene.	
Numerical Standards, Anthracene, 40.0900	The study tested concentrations at a range of temperature/dissolved oxygen combinations. It is unreasonable to use the temperature/dissolved oxygen combination that resulted in the greatest toxicity. Recommend using a median value for all studies (7.47 ug/L) rather than the lowest value identified (1.27 ug/L).	5,6,8	The most toxic concentration was observed at 20 degrees Celsius (69 degrees F) and 6.9 mg/L dissolved oxygen. MassDEP believes that the temperature/dissolved oxygen combination used for the standard is appropriate for the waters of Massachusetts. MassDEP re-reviewed the study and believes it is an appropriate basis.	
Numerical Standards, Chrysene, 40.0900	The study used for the GW-3 standard was inappropriate because: (1) determining toxic concentrations was not a goal of the study; and (2) controls were not used in the study.	5,6,8	MassDEP believes that data generated in this study are appropriate for the development of a GW-3 standard. MassDEP re-reviewed the study and also contacted the authors of the study. The authors confirmed that the study followed an ASTM protocol (as stated in the paper) and controls were in fact used. Study data were only used if corresponding control mortality was less than 10% (as specified in ASTM guidelines). The authors also confirmed that 0.7 ug/L chrysene represented a toxic concentration to Daphnia magna. 50% of the test population of Daphnia magna was immobilized at this concentration within 24 hours.	

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Reportable Concentrations, 40.1600	The reviewer enclosed summary tables of metals data in natural soils compiled from recent Haley and Aldrich projects in the Boston/Cambridge area and requested that MassDEP review the RCS-1 concentrations for metals and raise the nickel RCS-1 to at least 50 mg/kg. Natural marine clays and organic deposits contain 90 <sup>th</sup> percentile nickel concentrations of approximately 43 and 33 mg/kg, respectively, as compared to the current MCP 20 mg/kg RCS-1 value.	9	The Reportable Concentrations consider background levels that can be expected across the Commonwealth. Given that the Haley & Aldrich data set is limited to Boston and Cambridge, MassDEP does not believe it is appropriate to raise the nickel RC on the basis of this data set.
Numerical Standards, 40.0900	MassDEP specifically sought comment in the public hearing draft on the appropriate Practical Quantitation Limits (PQLs) to be used in setting standards for 1,4-dioxane to evaluate whether the proposed GW-1 and S/GW-1 standards were below the limits of what could be achieved by SW-846 Method 8260B, the analytical method specified in the Compendium of Analytical Methods (CAM) for 1,4-dioxane.  The reviewer commented that if a regulatory standard is established at a PQL, such PQL should be determined in a defined matrix using a specified method and should be no lower than the lowest calibration standard.	4, page 15	MassDEP agrees with the comment that PQLs employed in the standard setting protocol should be achievable considering the matrix and analytical method specified for a chemical. MassDEP believes that the proposed 1,4-dioxane GW-1 standard is achievable using a modification of the existing 8270C method that employs either solid or liquid phase extraction. Discussions of these modifications will be added to the CAM (in Method 8270B) as an analytical note. With respect to the proposed soil standards for 1,4-dioxane, MassDEP revised the PQL, and as a result, revised the standards upward from the proposed value of 0.005 to 0.2 ug/g. The revised standards reflect the effect of methanol preservation and the uncertainty in the extraction procedure on the quantitation limit. As part of its development of the final amendments, MassDEP also reviewed other proposed standards to ensure that each was analytically achievable using CAM specified methods, including methanol preservation, where applicable. Based on this review, MassDEP also revised the bromomethane S/GW-1 standards upward from 0.1 to 0.5 ug/g.

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Reportable Concentrations, 40.1600, MtBE	MassDEP specifically sought comment on the proposed RCGW-2 for MtBE. MassDEP had proposed to raise the RCGW-2 of 1 mg/l (1000 ug/l) that went into effect with the April 3, 2006 amendments, to 5 mg/l (5000 ug/l). The proposed change in the MtBE RCGW-2 value was intended to minimize notification of releases that ultimately do not require cleanup (because the RC is not based on the cleanup standards), while at the same time maintain a value low enough to provide early detection of gasoline plumes.	5, 8	The reviewers made an error in interpreting the units for the proposed MtBE RCGW-2. The proposed value is 5000 ug/l (or 5 mg/l), not 5 ug/l. The proposed value, therefore, is already well above the 70 ug/l RCGW-1 value.  No change was made to the proposed value of 5 mg/l.	
	The reviewers commented that the proposed increase in the RCGW-2 value from "1 to 5 ug/l" is well below the GW-1 concentration of 70 ug/l. The reviewers urged the Department to use the RCGW-1 value of 70 ug/l as the RCGW-2 value for MtBE.			

### Reference:

USEPA 2005 Final Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum. EPA/630/P-03/001F. US Environmental Protection Agency, Washington, D.C., March 2005.